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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,237	07/18/2003	Ronit Yahalomi	1662/611052	2876
26646	7590	10/05/2004	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			REYES, HECTOR M	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,237

Applicant(s)

YAHALOMI ET AL.

Examiner

Hector M Reyes

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 and 11 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 9, 12-21, 23-27, 29-34, 36-39 and 41-55 is/are rejected.
- 7) ☒ Claim(s) 5, 8, 22, 28, 35 and 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/16/04; 8/5/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of The Claims

Currently claims 1-55 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 4, 6, 7, 9, 15, 16, 19, 20-21, 23, 27, 29, 34 and 39 are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, the phrase "contacting a nateglinide in the solid state" is indefinite because it is not clear what is or are the polymorph or polymorphs required in the said process or if the said solid nateglinide is in amorphous form.

In claim 6, the phrase "preparing a solution of nateglinide in ethanol" is indefinite because it is not clear what is or are the polymorph or polymorphs required in the said process or if the said solid nateglinide is in amorphous form.

In claim 7, the phrase "a crystalline form of nateglinide in ethanol" is indefinite because it is not clear what is or are the polymorph or polymorphs required in the said process.

In claim 9 the phrase "storing nateglinide Form T for a sufficient time under suitable temperature" is obscure and indefinite because it is unclear what is the time or temperature limitations embraced in the said phrase. How much time would be sufficient time? Two hours? A day? Five years?

Art Unit: 1625

In claim 15, the phrase "preparing a solution of nateglinide in n-propanol" is indefinite because it is not clear what is or are the polymorph or polymorphs required in the said process or if the said solid nateglinide is in amorphous form.

In claim 16, the phrase "tritulating a crystalline form of nateglinide" is indefinite because it is not clear what is or are the polymorph or polymorphs required in the said process.

In claim 19, the phrase "The crystalline fomr or claim 18" is indefinite and lacks antecedent basis because there is no crystalline fomr in claim 18. Is Applicant's intention to further limit "The crystalline form of claim 18?

In claim 20, the phrase "preparing a crystalline form of nateglinide in iso-propyl alcohol" because it is not clear what is or are the polymorph or polymorphs required in the said process.

In claim 21 the phrase "tritulating a crystalline form of nateglinide" is indefinite because it is not clear what is or are the polymorph or polymorphs required in the said process.

In claim 23, the phrase "preparing a solution of nateglinide in iso-propanol and water" is indefinite because it is not clear what is or are the polymorph or polymorphs required in the said process or if the said solid nateglinide is in amorphous form.

In claim 27 the phrase "tritulating a crystalline form of nateglinide" is indefinite because it is not clear what is or are the polymorph or polymorphs required in the said process.

In claim 29, the phrase "preparing a solution of nateglinide in n-propanol" is indefinite because it is not clear what is or are the polymorph or polymorphs required in the said process or if the said solid nateglinide is in amorphous form.

Art Unit: 1625

In claim 34, the phrase "contacting a nateglinide in the solid state" is indefinite because it is not clear what is or are the polymorph or polymorphs required in the said process or if the said solid nateglinide is in amorphous form.

In claim 39 the phrase "tritulating a crystalline form of nateglinide" is indefinite because it is not clear what is or are the polymorph or polymorphs required in the said process.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 12-14, 17-19, 24-26, 30-33, 36-38 and 41-55 are rejected under 35 U.S.C.

103(a) as being unpatentable over:

- Sumikawa et al, US 5463116 (1995) or
- Sumikawa et al, US patent 5488150 (1996) or
- Gang et al, Acta Pharmaceutical Sinica, 36(7), pp 532-534 (2001) or

Sumikawa '116 and '150 disclose stable form of N-(trans-4-

isopropylcyclohexylcarbonyl)-D-phenylalanine, also known as Nateglinide which are

Art Unit: 1625

different from the B-type polymorph, see col. 1, lines 60-66. The said Crystal has been designated as the H-type. The said compounds are use in pharmaceutical compositions active in depressing blood glucose levels.

Gang discloses stable form of N-(trans-4-isopropylcyclohexylcarbonyl)-D-phenylalanine, also known as Nateglinide which are different from the B-type polymorph or H-type see page 532. The said crystal has been designated as the S-type. Gang also recognizes the biological active of nateglinide in lowering the blood glucose levels.

None of the cited references however disclose Nateglinide polymorphs designated as D, F, G, I, O, T or the methanol, ethanol or isopropanol, n-propanol or n-butanol solvates of nateglinide as described in the instant claims.

Nonetheless, a person skilled in the art at the time that the instant invention was made would be motivated to prepare alternative crystalline forms of a compound already known in the art in other crystalline forms, and to further use the said compound in pharmaceutical compositions useful in the biological activity or method already taught by the prior art.

Claims Objected

Claims 5, 8, 22, 28, 35 and 40 are objected because the said claims depend on rejected claims.

Allowable Subject Matter

Methods of preparation described in claims 10, 11 are found provisionally allowable since no prior art was found disclosing or suggesting the said methods.

Art Unit: 1625

CONCLUSION

Any inquiry concerning this communication should be directed to Hector M. Reyes whose telephone number is 571-272-0691. The examiner can normally be reached on Monday to Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Cecilia Tsang, whose phone number is 571-272-0562 or the Examiner's Primary, Ms. Rita Desai, whose telephone number is 571-272-0684. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 or for regular communication and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Héctor M. Reyes PhD, JD
USPTO Reg. # 54846
AU 1625
September 30, 2004.

R. Desai
9/30/04